Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: FDA Sample No. 3110447 (W/E 3913)
       Customs Entry No. W91-5315756-0
       Product: Cosmetics

WARNING LETTER

FLA-97-60

May 30, 1997

Robert Bassan, President
Tairo International
25 Southeast Second Avenue
Suite 1239
Miami, Florida   33131

Dear Mr. Bassan:

The Food and Drug Administration (FDA) attempted to examine a shipment of cosmetics offered for entry into the United States by your firm on January 30, 1997, under the above referenced entry number, and found that the shipment was not held intact. Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since this shipment was distributed without an FDA release, we have requested the U. S. Customs Service (Customs) to order redelivery of this shipment (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Robert Bassan
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Your written reply should be addressed to the Food and Drug
Administration, Attention: Paul R. Bagdikian, Compliance Officer,
P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen
Director, Florida District

Enclosure